

REMARKS

Please reconsider the application in view of the above amendments and the following remarks. Applicant thanks the Examiner for carefully reviewing this application.

Disposition of the Claims

Claims 58-83 are pending. Claims 58, 69, 71, and 72 have been amended. Claims 61, 64, 65, 70, and 77-83 have been previously withdrawn to remove non-elected subject matter. New claim 84 has been added. Therefore, claims 58-60, 62, 63, 66-69, 71-76, and 84 are under consideration. Claims 58 and 77 are independent. The remaining claims under examination at this time depend, directly or indirectly, from claim 58.

Claim Amendments

Claims 58, 69, 71, and 72 have been amended to clarify the invention. New claim 84 is added. Support of these amendments can be found, for example, FIGS. 4 and 4A, EXAMPLE 3, ¶¶ [0006], [0024], [0038], [0042], [0054], [0064]-[0066]¹. No new matter is introduced by these amendments.

Rejection(s) under 35 U.S.C. § 112**Claims 59 and 60**

Claims 59 and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the specification supports “pore size of about 20-2000 microns,” not “about 20 to 2000 microns;” and “a porosity of about 10-90%,” but

¹ The paragraph numbers are based on the U.S. Patent Application Publication No. 2005/0042253.

not “a porosity of about 10 to 90%.” Claims 59 and 60 have been amended. To the extent that this rejection may still apply to the amended claims, this rejection is respectfully traversed.

Claim 59 has been amended to recite, *inter alia*, “pore size of about 20-2000 microns.” Claim 60 has been amended to recite, *inter alia*, “a porosity of about 10-90%.” Therefore, claims 59 and 60 are supported by the specification. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 59 and 60

Claims 59 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner alleges that it is unclear if claim reads on “about 20” to “about 2000 microns” or to about “20 to 2000 microns.” Claims 59 and 60 have been amended to claim a pore size within the range of about 20-2000 microns. To the extent that this rejection may still apply to the amended claims, this rejection is respectfully traversed.

As noted above, claims 59 and 60 have been amended to read “pore size of about 20-2000 microns” and “a porosity of about 10-90%,” respectively. Therefore, claims 59 and 60 are not indefinite. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection(s) under 35 U.S.C. § 102Claims 58-60, 62, 63, 66 and 69-76

Claims 58-60, 62, 63, 66 and 69-76 are rejected under 35 U.S.C. 102(e) as being anticipated by King et al. U.S. Patent Publication 2004/0002770 (hereinafter "King"). Claim 58 has been amended. To the extent that this rejection may still apply to the amended claims, this rejection is respectfully traversed.

It is known in the art that, although porous ceramic materials have been used as bone graft substitutes, they are typically brittle, and thus, may not possess the mechanical strength needed for use in tissue fixation devices. (¶ [0005]).

The present invention relates to tissue fixation devices, which are initially non-porous. (¶ [0024], [0038], [0042], and [0054]). The devices are biodegradable and are substantially non-porous prior to implantation, providing a mechanically robust anchor during implantation and initial use. Typically, the devices, when initially implanted, do not have sufficient porosity to support tissue ingrowth. (¶ [0006]). Embodiments of the present invention include devices having an internal part, such as a plug, with interconnecting pores. In claimed embodiments, polymers are molded, e.g., by injection molding, into and around each plug to form a layer of polymers that covers the surface of the devices, providing mechanical strength needed for implantation. (FIGS. 4 and 4A, EXAMPLE 3, ¶ [0064]-[0066]).

To more clearly claim the invention, the amended claim 58 requires, *inter alia*, “a second component disposed in the pores of the first component, such that the first component is non-porous, wherein the second component further forms a non-porous layer that substantially covers the device.”

To be clear, the amended claims cover the embodiments, in which, for example, the first component has interconnecting pores and the second component fills the pores of the first component so that the first component becomes non-porous. Furthermore, the second component forms a substantially continuous non-porous layer of polymer around the outer surface of the non-porous first component. The result is a device having an outer layer that is initially non-porous substantially covering the device.

King teaches polymer-bioceramic structures for use in the repair of bone defects.

(Abstract). Specifically, King teaches:

[0014] The structures described herein may be fabricated by compression molding the polymer into the matrix, illustratively by squeeze-flow molding, or compression molding in manner to induce orientation of the polymer in multiple directions within the structure, or by in situ polymerization. The bioceramic matrix is sufficiently rigid to be used in compression molding processes. In addition, the structure described herein illustratively have high toughness, high creep resistance, and high flexibility. (Emphasis added).

King does not teach or suggest “a second component disposed in the pores of the first component, such that the first component is non-porous, wherein the second component further forms a non-porous layer that substantially covers the device,” as required by claim 58. King does

not teach a layer substantially surround an inner component. King teaches filling the pores of an inner part, but does not teach a substantially continuous layer around the entire surface of the inner part.

To anticipate a claim, the prior art reference must disclose every limitation of the claim. Because King fails to teach or suggest at least one limitation of the amended claim 58, the amended claim 58 is patentable over King. The remaining dependent claims including new claim 84 should also be patentable for at least the same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 58-60, 62, 63, 66 and 70-74

Claims 58-60, 62, 63, 66 and 70-74 are rejected under 35 U.S.C. 102(a)² as being anticipated by Beam et al. U.S. Patent No. 7,122,057 (hereinafter "Beam"). Claim 58 has been amended. To the extent that this rejection may still apply to the amended claims, this rejection is respectfully traversed.

Beam teaches engineered regenerative biostructures for implantation into human body as bone substitutes. (Abstract). Specifically, Beam teaches:

"One method for increasing the strength of the biostructure is to perform a processing step or steps to either partially or completely fill open pores in the biostructure with another substance or substances. One purpose of such additional substance may be to increase mechanical strength. Such a strengthening substance may be fibrin or fibrinogen, or polymers or other substances, examples of which are given herein. Poly lactic co-glycolic acid

² Beam was issued on October 17, 2006, which is after the filing date of the present invention, i.e., August 22, 2003. Thus, Beam cannot be a prior art reference under 102(a).

and related substances may also be used." (Col. 21, lines 51-59, emphasis added).

Beam does not teach or suggest "a second component disposed in the pores of the first component, such that the first component is non-porous, wherein the second component further forms a non-porous layer that substantially covers the device," as required by claim 58. Beam does not teach a layer substantially surround an inner part. Beam teaches filling the pores of an inner part, but does not teach a substantially continuous layer around the entire surface of the inner part.

To anticipate a claim, the prior art reference must disclose every limitation of the claim. Because Beam fails to teach or suggest at least one limitation of the amended claim 58, the amended claim 58 is patentable over Beam. The remaining dependent claims including new claim 84 should also be patentable for at least the same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection(s) under 35 U.S.C. § 103(a)

Claims 58-60, 62, 66 and 69-74

Claims 58-60, 62, 66, and 69-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown 2003/0003127 (hereinafter "Brown"). Claim 58 has been amended. To the extent that this rejection may still apply to the amended claims, this rejection is respectfully traversed.

Under the current law of obviousness, including under the Supreme Court's *KSR* decision, an obviousness rejection cannot be based on a combination of references to show the

claimed subject matter where the references sought to be combined teach one of ordinary skill in the art away from combining them. This was reiterated by the Supreme Court in KSR as follows:

In United States v. Adams, 383 U.S. 39, 40, 86 S. Ct. 708, 15 L. Ed. 2d 572, 174 Ct. Cl. 1293 (1966), a companion case to *Graham*, the Court considered the obviousness of a "wet battery" that varied from prior designs in two ways: It contained water, rather than the acids conventionally employed in storage batteries; and its electrodes were magnesium and cuprous chloride, rather than zinc and silver chloride. The Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result. 383 U.S., at 50-51, 86 S. Ct. 708, 15 L. Ed. 2d 572, 174 Ct. Cl. 1293. It nevertheless rejected the Government's claim that Adams' battery was obvious. The Court relied upon the corollary principle that *when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious.* Id., at 51-52, 86 S. Ct. 708, 15 L. Ed. 2d 572, 174 Ct. Cl. 1293. When Adams designed his battery, *the prior art warned that risks were involved in using the types of electrodes he employed. The fact that the elements worked together in an unexpected and fruitful*

manner supported the conclusion that Adams' design was not obvious to those skilled in the art.

KSR Int'l v. Teleflex, Inc., 550 U.S. 398, 416 (2007) (emphasis added). As further help by US courts: "Rather than being made obvious by the reference, such modification would run counter to its teaching by rendering the apparatus inoperative." In re Schulpfen, 157 USPQ 52 (CCPA 1968).

Claim 58 requires, *inter alia*, "a second component disposed in the pores of the first component, such that the first component is non-porous, wherein the second component further forms a non-porous layer that substantially covers the device."

Brown teaches composite scaffolds with a porous ceramic phase and a porous polymer phase. (Abstract). The Examiner asserts that "Brown teaches that the polymer phase infiltrates the macropores of the ceramic phase, para. 0026, forming a solid interlocking perform [*sic*] structure. As such, it is substantially non-porous prior to implantation into a patient, where the second component has a higher rate of in vivo degradation." (Office Action, page 8).

Applicant respectfully disagrees.

Brown teaches that "[t]he present invention relates to bi- or multi-layered scaffolds with a porous, bioabsorbable polymer layer attached to a porous ceramic layer via a porous transitional interface...The present invention can be utilized to repair/regenerate a tissue junction by inducing one cell type to proliferate in the polymer phase of the scaffold and a second cell type to grow in the ceramic phase of the scaffold." (§ [0022], emphasis added).

Brown further teaches the importance of these porous layers: “[t]he interconnecting pores and channels facilitate the transport of nutrients and/or invasion of cells into the scaffold, facilitating the ingrowth of tissue.” (¶ [0023], emphasis added).

Therefore, Brown’s scaffold “can include...(4) multi-layer composite structures with layers of alternating porous ceramics and polymers;...and/or (7) cells which may be cultured prior to or at the time of implantation.” (¶ [0025], emphasis added).

Clearly, the purpose of Brown’s porous layers of the scaffolds and polymers is to facilitate nutrient transport and cell invasion. Thus, Brown’s scaffolds and polymers must be porous prior to or at the time of implantation to allow cells to grow in the pores in the polymer phase and/or the ceramic phase of the scaffold. In other words, Brown *teaches away* having an outer layer that is non-porous for the purpose of improving mechanical strength. One skilled in the art having read Brown would not be motivated to substitute Brown’s porous layers with non-porous layers, because such a substitution would not facilitate nutrient transport and cell invasion, thus, defeating the purpose of Brown and, in fact, rendering Brown’s scaffolds and polymers inoperative.

As a result, Brown does not teach or suggest “a second component disposed in the pores of the first component, such that the first component is non-porous, wherein the second component further forms a non-porous layer that substantially covers the device,” as required by claim 58. Thus, in addition to teaching away from the claimed invention, Brown does not teach or suggest all the limitations of claim 58. Therefore, claim 58 is patentable over Brown. The

remaining dependent claims including new claim 84 are also patentable for at least the same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 67 and 68

Claims 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over King, Brown, or Beam. Claim 58 has been amended. To the extent that this rejection may still apply to the amended claims, this rejection is respectfully traversed.

As noted above, none of King, Brown, or Beam teach or suggest “a second component disposed in the pores of the first component, such that the first component is non-porous, wherein the second component further forms a non-porous layer that substantially covers the device,” as required by claim 58. The combination of King and/or Beam to the previously discussed lack of obviousness over Brown cures none of the deficiencies of that prior 103(a) rejection. Neither King nor Beam, alone or combined, teach against the clear teaching away from the claimed invention by Brown. Accordingly, claim 58 is patentable over King, Brown, and/or Beam. Claims 67 and 68 depend from claim 58. Therefore, claims 67 and 68 are also patentable for at least the same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

Conclusion

Applicant believes this reply is fully responsive to all outstanding issues and places this application in condition for allowance. If this belief is incorrect, or other issues arise, the Examiner is encouraged to contact the undersigned or his associates at the telephone number listed below. Please apply any charges not covered, or any credits, to Deposit Account 50-0591 (Reference Number 17771/002002).

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Respectfully submitted,

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